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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,580	05/22/2000	Frank McKeon	HMSU-P01-048	1156

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/575,580	MCKEON ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-10,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 June 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 8-10 and 12-13 are pending.

Applicants' amendment filed June 22, 2005 is acknowledged. Applicants' response has been fully considered. Claim 11 has been cancelled. Therefore, claims 8-10 and 12-13 are examined. A proposed Examiner's Amendment has been faxed to the applicant on November 17, 2005, however, the proposed amendment has not been accepted.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claim 11 under 35 U.S.C. 112, first and second paragraphs, is withdrawn in view of applicants' cancellation of the claim, and applicants' response at page 3 in the amendment filed June 22, 2005.

Informalities

The disclosure is objected to because of the following informalities:

3. A new set of drawings filed on June 02, 2003 is acknowledged, however, some letters in Fig. 1A are not clearly shown and hard to read. Appropriate correction is required.

4. The specification recites amino acid sequences, e.g., LISPPxSP at page 6, line 25; RRPE at page 54, line 5 and page 127, line 26, however, there are no sequence identifiers "SEQ ID NO:" provided. Applicants must comply with the requirements of the sequence rules (37 CFR 1.821-1.825) and provide a paper copy and computer readable form of Sequence Listing containing all the sequences.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 8-10 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying a compound that modulates the activity or level of a calcipressin (Csp) protein, the method comprising contacting a cell comprising a Csp protein with a test compound and determining the activity or level of the Csp protein in the cell, wherein a higher or lower activity or level of the Csp protein in cell contacted with the test compound relative to a cell that was not contacted with the test compound indicates that the test compound is a compound that modulates the activity or level of the Csp protein, wherein said activity of the Csp protein is the binding or inhibition of the Csp protein to calcineurin, and wherein the Csp protein consists of the amino acid sequence of SEQ ID NO:4 (Csp 1) or SEQ ID NO:5 (Csp 2), does not reasonably provide enablement for a method of identifying a compound that modulates the activity or level of a calcipressin (Csp) protein, the method comprising contacting a cell comprising a Csp protein with a test compound and determining the activity or level of the Csp protein in the cell, wherein a higher or lower activity or level of the Csp protein in cell contacted with the test compound relative to a cell that was not contacted with the test compound indicates that the test compound is a compound that modulates the activity or level of the Csp protein, wherein said activity of the Csp protein is the binding or inhibition of the Csp protein to calcineurin, but the sequence of the Csp protein is not defined. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 8-10 and 12-13 encompass a method of identifying a compound that modulates the activity or level of a calcipressin (Csp) protein, the method comprising contacting a cell comprising a Csp protein with a test compound and determining the activity or level of the Csp protein in the cell. The specification, however, only discloses cursory conclusions without data supporting the findings, which state that the specification provides assays for screening test compounds to identify molecules that modulate protein level or activity, and the method comprising incubating a cell expressing Csp with a test compound and measuring the Csp mRNA or protein level, where the Csp protein level, for example, can be determined by immunoprecipitation or immunohistochemistry using an antibody that specifically recognizes Csp (page 16, line 4-page 17, line 19; page 104, lines 6-15). There are no indicia that the present application enables the full scope of the claims in view of a method of identifying a compound that modulates the activity or level of a Csp protein as discussed in the stated rejection. The present application does not provide sufficient teaching/guidance as to how the full scope of the claims is encompassed. The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breadth of the claims, the presence or absence of working examples, the state of the prior art and relative skill of those in the art, the predictability or unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breadth of the claims:

The breadth of the claims is broad and encompasses unspecified variants regarding the identities of the Csp proteins used in the claimed method, which are not adequately described or demonstrated in the specification.

(2). The absence or presence of working examples:

The specification indicates a two-hybrid screen system can be used to monitor the binding or inhibition of a Csp protein to calcinurein (pages 123-125; Fig. 1); Csp-calcinurin interactions may be determined via immunoprecipitation (page 135, lines 16-26); the inhibition of a Csp protein to inhibit calcinurein may also be determined by assaying the effect of a Csp protein on the nuclear import of NF-AT (pages 125-128: Fig. 2); and cyclosporine A abolished the induction of Csp 1 transcripts in cells by ionomycin, supporting the notion that the Csp 1 transactivation process is dependent on calcineurin activation rather than other calcium activated factors (pages 129, line 20-page 130, line 20; Fig. 16). However, the specification has not demonstrated using various Csp proteins with defined sequences in the claimed method.

(3). The state of the prior art and relative skill of those in the art:

The prior art (e.g., Barford, TIBS 21, 404 (1996); page 1 of the specification) indicates calcineurin plays a pivotal role in signal transduction, and the present invention relates to the discovery of a family of endogenous inhibitors of calcineurin, named calcipressins, Csp1 (SEQ ID NO:4), Csp2 (SEQ ID NO:5) and Csp3 (SEQ ID NO:24; page 12, lines 14-18; Table 1); and some monoclonal antibodies are produced to specifically recognize Csp 1 and Csp 2 (pages 133-134). However, the general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide teachings on the identities of various functional Csp proteins used in the claimed method to be considered enabling for variants.

(4). Predictability or unpredictability of the art:

The claims encompass a method of identifying a compound that modulates the activity or level of a Csp protein, and the specification discloses the amino acid sequences of Csp1 (SEQ ID NO:4), Csp2 (SEQ ID NO:5) and Csp3 (SEQ ID NO:24; Table 1) and some monoclonal antibodies are produced to specifically recognize Csp 1 and Csp 2 (pages 133-134). However, the identities of various Csp proteins used in the claimed method are not adequately described in the specification, the invention is highly unpredictable regarding the sequence of a functional Csp protein.

(5). The amount of direction or guidance presented and the quantity of experimentation necessary:

The claims are directed to a method of identifying a compound that modulates the activity or level of a Csp protein. The specification indicates a two-hybrid screen system can be used to monitor the binding or inhibition of a Csp protein to calcinurein (pages 123-125; Fig. 1); Csp-calcinurin interactions may be determined via immunoprecipitation (page 135, lines 16-26); the inhibition of a Csp protein to inhibit calcinurein may also be determined by assaying the effect of a Csp protein on the nuclear import of NF-AT (pages 125-128: Fig. 2); and cyclosporine A abolished the induction of Csp 1 transcripts in cells by ionomycin, supporting the notion that the Csp 1 transactivation process is dependent on calcineurin activation rather than other calcium activated factors (pages 129, line 20-page 130, line 20; Fig. 16). However, the specification has not demonstrated using various Csp proteins with defined sequences in the claimed method. Since the specification does not provide sufficient teachings on the identities of various functional Csp proteins, it is necessary to carry out undue experimentation to identify the

functional Csp protein and to use these functional Csp proteins to identify compounds that modulate the activity or level of a Csp protein in the claimed method.

(6). Nature of the Invention

The scope of the claims encompasses a method of identifying a compound that modulates the activity or level of a Csp protein, but the specification does not provide sufficient teachings on identification of various functional Csp proteins used in the claimed method. Thus, the disclosure is not enabling for the reasons discussed above.

In summary, the scope of the claim is broad, the working examples do not demonstrate the claimed methods associated with variants, the teaching in the specification is limited, and the sequence of a functional Csp protein is not predictable, and therefore, it is necessary to carry out undue experimentation to identify a functional Csp protein used in claimed method.

Conclusion

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CHIH-MIN KAM
PATENT EXAMINER

CMK
December 30, 2005